

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC. and)	
KAI PHARMACEUTICALS, INC.,)	
)	
Plaintiffs,)	C.A. No. 21-662 (MN)
)	(Consolidated)
v.)	
AUROBINDO PHARMA LIMITED, et al.,)	REDACTED - PUBLIC VERSION
)	Original Filing Date: December 14, 2022
Defendants.)	Redacted Filing Date: December 20, 2022

STIPULATION AND ORDER

Plaintiffs Amgen Inc. and KAI Pharmaceuticals, Inc. (“Plaintiffs”), and Defendant USV Private Limited (“USV”), stipulate and agree as follows:

1. USV has filed Abbreviated New Drug Application (“ANDA”) No. 216930 with the United States Food and Drug Administration seeking approval for USV’s generic version of Parsabiv® (etelcalcetide) injection for intravenous use at strengths of 2.5 mg/0.5 mL, 5 mg/mL, and 10 mg/2 mL (“USV’s Proposed ANDA Product”).

2. Plaintiffs have sued USV for patent infringement, asserting that the submission of USV’s ANDA No. 216930 constitutes an act of infringement of U.S. Patent Nos. 9,820,938 (“the ’938 patent”); 10,344,765 (“the ’765 patent”); and 11,162,500 (“the ’500 patent”). USV has asserted various defenses and counterclaims in response to Plaintiffs’ Complaint.

3. The parties wish to narrow the issues in dispute and have reached agreement on the infringement issues set forth below.

4. Specifically, the parties stipulate and agree that USV’s submission of ANDA No. 216930 infringed, and the making, using, offering to sell, selling, or importing of USV’s Proposed ANDA Product will infringe or induce infringement of the following claims of the following patents, so long as each respective claim is not found invalid or unenforceable:

- a. Claims [REDACTED], and [REDACTED] of the '938 patent;
- b. Claims [REDACTED], and [REDACTED] of the '765 patent; and
- c. Claims [REDACTED], and [REDACTED] of the '500 patent.

5. Plaintiffs are not asserting any claims of the '938, '765, or '500 patents against USV in this action other than those identified in Paragraph 4 herein based on the filing of USV's Proposed ANDA Product or based on the making, using, offering to sell, selling, or importing of USV's Proposed ANDA Product as currently described in USV's ANDA No. 216930.

6. Plaintiffs hereby agree not to further pursue fact discovery from USV in this case with respect to the above-listed patents regarding the manufacturing or preparation of the etelcalcetide hydrochloride active pharmaceutical ingredient used in making USV's Proposed ANDA Product; DMF No. 035768 for etelcalcetide hydrochloride; samples of the etelcalcetide hydrochloride API used in USV's Proposed ANDA Product; samples of any finished dosage form of USV's Proposed ANDA Product; the formulation of USV's ANDA Product, including fact discovery regarding the manufacturing of, excipients used in, quantity of any excipient in, or function of any excipient in USV's Proposed ANDA Product. The parties agree that Amgen may still take discovery regarding USV's development of its Proposed ANDA Product.

7. Plaintiffs have noticed the deposition of USV pursuant to Rule 30(b)(6) (Dkt. 105). Upon completion of that deposition of USV, should Plaintiffs believe they need an additional deposition of a USV fact witness in his or her individual capacity, the parties shall meet and confer regarding the identity of such witness and negotiate in good faith to make such witness available for deposition. The parties agree that, if the deposition of the additional USV fact witness proceeds, it may take place outside of the time period set for fact discovery in the Court's

Scheduling Order (Dkt. 115). USV agrees that it will not call any individual listed in USV's Initial Disclosures Pursuant to Rule 26(a)(1) to testify at trial unless that person has been deposed in an their individual capacity.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Cameron P. Clark

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December 14, 2022

SO ORDERED this ____ day of _____, 2022.

UNITED STATES DISTRICT JUDGE